

REMARKS

FORMAL MATTERS:

Claims 1-2, 4, 6, 8-11, 15, and 19-30 as well as new claims 31-33 are pending after entry of the amendments set forth herein.

Claims 3, 5, 7, 12-14, and 16-18 are canceled without prejudice.

Claims 1, 9-10, and 15 are amended. Claims 31-33 are added. Support for these amendments is found in the specification at, for example, page 7, paragraph 26, page 8, paragraph 35, page 9, paragraph 38, page 10, paragraph 44, page 12, lines 1-2 of paragraph [0051]; page 13, paragraph [0054]; page 16, lines 1-3 of paragraph [0070]; page 18, paragraph 79; page 21, lines 1-3 of paragraph [0091], lines 1-2 of paragraph [0093].

The Applicants submit that the amendments directed towards the synergistic effect of administering the iSe compound and radiation therapy were presented in the Supplemental Amendment filed on October 22, 2009. However, these amendments were inadvertently omitted from the claims in the response filed on April 28, 2010. The claims as presented herein reintroduce the amendments originally presented in the Supplemental Amendment filed on October 22, 2009.

No new matter is added.

REJECTIONS UNDER §102

Claims 1-2, 6, 8-11, 19, 20-26, and 27 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Hehr et al. (Med. Klin. (Munich) (1997), Vol. 92 Suppl. No. 3, pp. 48, 49; Abstract) (hereinafter “Hehr”). The Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, (Fed. Cir. 1987).

The Office cites the abstract of Hehr for allegedly disclosing administering 400 micrograms of sodium selenite after every course of irradiation of rectal tumor regions and lymph nodes. The Office further states that “Although the claim indicates that

radiation therapy is administered after administering the inorganic selenium compound, since inorganic selenium is administered after every course of radiation, the prior art method meets the claims as once the second course of radiation is given this would have occurred after administration of an inorganic selenium dose”.

As amended, the rejected claims require, *inter alia*, administering radiation therapy to the subject within 6 hours after the iSe compound is administered.

Hehr fails to disclose each and every element of the rejected claims. For example, Hehr does not disclose administering radiation therapy to the subject within 6 hours after the iSe compound is administered.

As such, Hehr cannot anticipate Claims 1-2, 6, 8-11, 19, 20-26, and 27 under §102. Accordingly, this rejection should be withdrawn. Withdrawal of this rejection is respectfully requested.

REJECTIONS UNDER §103(A)

Claims 1-2, 4, 6, 8-11, 15, and 19-30 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Stiefel et al. (U.S. Patent No. 6,656,509) in view of Lemelson (U.S. Patent No. 4,665,897), Gorun (U.S. Patent No. 6,511,971), and Hehr (*supra*). The Applicants respectfully traverse this rejection.

In order to meet its burden in establishing a rejection under 35 U.S.C. §103, the Office must first demonstrate that a prior art reference, or references when combined, teach or suggest all claim elements. *See, e.g., KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007); *Pharmastem Therapeutics v. Viacell et al.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); MPEP § 2143(A)(1).

The Office cites Stiefel for allegedly teaching a method for producing a synergistic cytotoxic effect on a cancer cell in a patient by contacting the cell with a salt of SeO₂ and a cytostatic agent, wherein the administration is simultaneous, separate, or sequential. The Office cites Lemelson for allegedly teaching use of antibodies that target tumor tissue and contain nucleide that can be rendered radioactive by a beam of neutron thereby destroying the cancerous tissue. The Office cites Gorun for allegedly teaching treating tumors with photodynamic sensitizers which produce singlet molecular oxygen and destroys the cancerous tissue. The Office states that Hehr discloses administering

400 micrograms of sodium selenite after every course of irradiation of rectal tumor regions and lymph nodes. The Office concludes that one of ordinary skill in the art would have expected the combination of sodium selenite with other methods of treatment of cancer would be effective in treating cancer, including when radiation therapy is administered after inorganic selenium administration.

As amended, the rejected claims require, *inter alia*, administering radiation therapy to the subject within 6 hours after the iSe compound is administered.

None of the cited references alone or in any combination teach or even suggest administering radiation therapy to the subject within 6 hours after the iSe compound is administered.

Since the combination of the cited references fails to teach or suggest all of the claim elements, this combination cannot render the rejected Claims 1-2, 4, 6, 8-11, 15, and 19-30 obvious under §103(a).

As such, this rejection should be withdrawn. Withdrawal of this rejection is respectfully requested.

Newly presented Claims 31-33 are patentable at least for the foregoing reasons.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Carol Francis at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-333.

Respectfully submitted,

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